DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 3, 2014

InMode MD LTD.
% Ms. Ahava Stein
A. Stein – Regulatory Affairs Consulting LTD.
20 Hata'as Street, Suite 102
Kfar Saba 44425
Israel

Re: K140926
Trade/Device Name: InMode WMface Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 21, 2014
Received: October 29, 2014

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 140926

Device Name: InMode WMface Device

Intended Use Statement:

The InMode WMface device is intended for use in dermatologic procedures, for noninvasive treatment of mild to moderate facial wrinkles and rhytides.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D)

OR

Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

INMODE WMFACE DEVICE

510(k) Number K140926

Applicant Name:

Company Name: InMode MD Ltd.
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Date Prepared: 25 November 2014

Trade Name: InMode WMface Device

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The InMode WMface device is substantially equivalent to the following predicate devices.

Manufacturer	Device	510(k) No.
EndyMed Ltd.	Imagine TC Skin Treatment System	K083461

Device Description:

The InMode WMface device is designed to deliver radio frequency (RF) energy which is emitted into the skin in a uniform manner, via two pairs of bi-polar electrodes. RF energy heats the tissue to trigger collagen remodeling for the treatment of wrinkles and rhytides.

The InMode WMface device is designed to deliver RF energy to the skin. The device provides individual adjustment of RF power to achieve maximum efficiency and safety for each patient. The ergonomic hand piece allows efficient treatment of the skin

The InMode WMface device consists of an AC/DC power supply unit, RF generator, controller and user interface including a LCD screen and functional buttons. The hand piece is connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The hand piece comprises a handle and two pairs of electrodes.

Following are the InMode WMface device specifications:
RF Output Power: 10-65 Watt
RF Output Frequency: 1[MHz] ± 2%
Dimension: 46 x 46 x 100 cm (18.2 x 18.2 x 40 in)
Weight: 30 Kg (66 lbs)
Main Line Frequency (nominal): 50-60 Hz
Input Voltage (nominal): 100-240 VAC

Intended Use/Indication for Use:

The InMode WMface device is intended for use in dermatologic procedures for noninvasive treatment of mild to moderate facial wrinkles and rhytides.

Performance Standards:

The InMode WMface Device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005; + CORR. 1 (2006) + CORR. 2 (2007)/ EN 60601-1:2006
- IEC 60601-1-2 (2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests; and IEC 60601-2-2 (2009): Medical Electrical Equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (section 202.6.1 (Emission) and section 202.6.2 (Immunity).
- IEC 60601-2-2 (2009): Medical Electrical Equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment; for use in conjunction with IEC 60601-1:2005

Sterilization, Cleaning and Biocompatibility:

The InMode WMface device is not supplied sterile or sterilized by the user. The device is intended for multiple use and therefore, it must be cleaned according to the instructions provided in the Instruction For Use. The InMode WMface hand piece comes in contact with the skin surface. All device materials in contact with the skin surface are biocompatible.

Non-Clinical (Bench) Performance Data:

Several performance tests were conducted to evaluate the effectiveness and safety of the InMode WMface device and its equivalence to the predicate device. A bench test was performed to measure the accuracy of the RF output parameters in the InMode WMface device and compare them to the RF output measurements in the predicate device (EndyMed Imagine TC Skin Treatment System). The results of the bench test demonstrated that the InMode WMface device has the same RF output specifications as the predicate device and therefore, is substantially equivalent to the predicate device.

An additional bench test was performed to demonstrate that the InMode WMface device and the predicate device consistently maintain the skin temperature below the specified temperature limit during the recommended treatment period and using different RF output power settings. The results demonstrated that both devices tested at the same RF energy outputs maintain the skin temperature below the specified temperature limit.

An additional ex-vivo test was performed to evaluate and compare the thermal energy distribution generated by the WMface device and the EndyMed Imagine System. The testing performed on a porcine tissue model using different RF output power settings and time intervals demonstrated an identical energy distribution pattern, penetration depth and maximal temperature in both devices.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the InMode WMface device are substantially equivalent to the indications for use and technological characteristics of the EndyMed Imagine TC Skin Treatment System.

The design and components in the InMode WMface device, including the console (with power supply, RF generator, controller and display panel) and the hand piece applicator (with cable and connector to console) are similar to the design and components found in the predicate EndyMed Imagine TC Skin Treatment System. The minor differences are insignificant and do not influence the safety or efficacy of the device as shown in the performance tests provided in section 18. The performance specifications (including frequency, RF output power and pulse duration) of the InMode WMface device are

substantially equivalent to those in the EndyMed Imagine TC Skin Treatment System. Both devices demonstrated similar temperature and thermal profiles behaviors as was shown in the performance tests. The safety features and compliance with safety standards in the InMode WMface device are similar to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also similar. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new InMode WMface device underwent performance testing, including software validation testing (provided in Section 16) and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 (provided in Section 17) and bench tests (provided in Section 18). These performance tests demonstrated that the minor differences in the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode WMface device is substantially equivalent to the predicate EndyMed Imagine TC Skin Treatment System, cleared under 510(k) K083461, and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate devices, the InMode WMface device is substantially equivalent to the EndyMed Imagine TC Skin Treatment predicate device.